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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,932

05/05/2006

Yechezkel Barenholz

BARENHOLZ14

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EXAMINER

EPSS -SMITH, JANET L

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,932	Applicant(s) BARENHOLZ ET AL.	
	Examiner JANET L. EPPS -SMITH	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-70, 72-82, 84, 85, 87-98 and 100 is/are pending in the application.
- 4a) Of the above claim(s) 84, 85, 87-98 and 100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-70 and 72-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/28/10</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims

2. Claims 61-70, 72-82 and 84-85, 87-98, and 100 are pending.

3. Applicants have amended claims 61, 84, and 88 to recite the compound recited in claim 71. According to Applicants, the present amendment places the elected claim in condition for allowance. Moreover, Applicants argue that because all of the non-elected claims share the special technical feature of the compound set forth in original claim 71, it is appropriate for the examiner to now reconsider the lack of unity of rejection and consider and allow all of the claims now present in the case.

4. Contrary to Applicant's assertions, all of the instant claims are not in condition for allowance. Rejoinder of claims 84-85, and 87, would raise new issues under 35 USC 112, 1st ¶. The elected claims are drawn to the simple delivery of nucleic acid to a cell. Claims 84-85 and 87 encompass the treatment of any disease or disorder by the delivery of a non-specific nucleic acid in combination with the compounds of the present invention. Additionally, the rejoinder of the product claims, claims 88-98 and 100 would raise a new ground of rejection under Obvious type Double Patenting.

5. Claims 84-85, 87-98, and 100 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/01/2009.

Claim Rejections - 35 USC § 102

6. The rejection of claims 61-62, and 65-82 under 35 U.S.C. 102(e) as being anticipated by Barenholz et al. (US2008/0112917A1), is withdrawn in response to Applicant's arguments.

7. The rejection of claims 61-62, and 65-70 under 35 U.S.C. 102(b) as being anticipated by Jorgensen et al. U.S. PreGrant Pub. No. 2002/0188023 A1, published December 12, 2002, is withdrawn in response to Applicant's amendment to the claims.

Claim Rejections - 35 USC § 103

8. Applicant's arguments with respect to the rejection of claims 61-70 under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. U.S. PreGrant Pub. No. 2002/0188023 A1, or Barenholz et al. (US2008/0112917A1) in view of Wheeler et al. (US 5,976,567) have been considered but are moot in view of the new ground(s) of rejection.

9. Claims 61-70, and 72-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. WO 97/45442 , Jorgensen et al. U.S. PreGrant Pub. No. 2002/0188023 A1, and Wheeler et al. (US 5,976,567).

10. Miller et al. teaches a composition comprising a lipid-polyalkylamine conjugate. [Entire reference, in particular.] [Figure 5, in particular.] The lipid that Miller et al. teaches is cholesterol. The polyalkylamine that Miller et al. teaches includes spermine and spermidine and its analogs. [Figure 4, in particular.] Miller et al. also teaches the use of carbamoyl group to link the lipid-polyalkylamine conjugate. [Figure 5, in

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particular.] In the instant case, Miller et al. teaches a composition comprising cholesterol carbamoyl spermine and its analogs.

11. Miller et al. did not teach the use of ceramide as the lipid. However, at the time the invention was made, Jorgensen et al. teaches the use of ceramide as an alternative lipid to cholesterol. [Paragraph 0064, in particular.] Jorgensen et al. establishes that cholesterol and ceramide can be used in place of each other, art recognized equivalents. Therefore, it would have been prima facie obvious for one of ordinary skill in the art to use ceramide as the lipid in the lipid-polyalkylamine conjugate of Miller et al. In the instant case, both Miller et al. and Jorgensen et al. teach that lipid-polyalkylamine compound is a cationic liposome that can be used to facilitate delivery of therapeutic agents such as DNA, mRNA, antisense oligonucleotides, proteins and drugs into cells. Additionally, the use of ceramide in place of cholesterol renders the compound of Miller et al. as ceramide carbamoyl-spermine (CCS). One of ordinary skill in the art would have been motivated to do to make a composition that facilitates delivery of therapeutic agents. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of one lipid for another, art recognized equivalents, is routinely practiced in the art.

12. Neither Miller et al. nor Jorgensen et al. include a biologically active molecule with the composition. However, as noted above, both teach that the compound is a cationic liposome that can be used to facilitate delivery of therapeutic agents such as DNA, mRNA, antisense oligonucleotides, proteins and drugs into cells. Additionally, Wheeler et al. teach lipopolyamine compositions comprising nucleic acid for use in

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methods involving the transfer of nucleic acid into cells. Wheeler specifically teaches that exogenous nucleic acid such as dsRNA, dsDNA, ssRNA, ssDNA, and cloned DNA in the form of a vector such as a plasmid or viral genome, may be combined in a transfection complex.

13. Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to include plasmid or siRNA nucleic acid with the lipid-polyalkylamine conjugates of Miller et al. or Jorgensen et al. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to facilitate the delivery of these molecules into cells. One of ordinary skill in the art would have had a reasonable expectation of success for doing so because Jorgensen et al. discloses that lipid-polyalkylamine conjugates are effective to facilitate delivery of drugs into cells.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. EPPS -SMITH whose telephone number is (571)272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633